

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

**JANSSEN PHARMACEUTICA N.V.,  
JANSSEN, L.P., and  
SYNAPTECH, INC.**

**Plaintiffs,**

**V.**

**TEVA PHARMACEUTICALS USA, INC. and  
TEVA PHARMACEUTICAL INDUSTRIES  
LTD.,**

**Defendants.**

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**Civil Action No. 05-356 (KAT)**

**ANSWER AND COUNTERCLAIMS OF DEFENDANT**  
**TEVA PHARMACEUTICALS USA, INC.**

Defendant Teva Pharmaceuticals USA, Inc. (“Teva USA”) answers the Complaint of Janssen Pharmaceutica N.V., Janssen, L.P. (collectively, “Janssen”), and Synaptech, Inc. (collectively, “Plaintiffs”) as follows:

1. Teva USA states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 1 of the Complaint, and on that basis denies the allegations set forth therein.

2. Teva USA states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 2 of the Complaint, and on that basis denies the allegations set forth therein.

3. Teva USA states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 3 of the Complaint, and on that basis denies the allegations set forth therein.

4. Teva USA admits that it is a corporation incorporated and existing under the laws of the State of Delaware, having a principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania, 19454. Teva USA denies the remaining allegations set forth in Paragraph 4 of the Complaint.

5. Teva USA admits that Teva USA is a wholly owned indirect subsidiary of Teva Pharmaceutical Industries Ltd. ("Teva Ltd."), which is a corporation organized and existing under the laws of Israel with a principal place of business in Israel. Teva USA denies the remaining allegations set forth in Paragraph 5 of the Complaint.

6. Teva USA admits that it filed an abbreviated new drug application ("ANDA") No. 77-587 for galantamine hydrobromide tablets. Teva USA further admits that portions of its ANDA No. 77-587 are derived from information provided to it by Teva Ltd. Teva USA further admits that, in the event that the United States Food and Drug Administration ("FDA") approves Teva USA's ANDA, Teva USA intends to market and sell such galantamine hydrobromide tablets. Teva USA further admits that it markets and sells pharmaceutical products, including generic prescription drug products manufactured and sold pursuant to approved ANDAs. Teva USA denies the remaining allegations set forth in Paragraph 6 of the Complaint.

7. Teva USA admits that Plaintiffs filed a civil action asserting patent infringement arising under Title 35 of the United States Code, for alleged infringement of United States Patent No. 4,663,318 ("the '318 patent"). Teva USA denies that Plaintiffs' claims are valid or have merit. Teva USA further admits that, with respect to the claims against Teva USA, this Court

has jurisdiction over the subject matter of Plaintiffs' claims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. Teva USA admits that this Court has jurisdiction over Teva USA for the purposes of this action.

9. The allegations contained in Paragraph 9 of the Complaint are not directed to Teva USA and, accordingly, no response is required.

10. Teva USA admits that venue is proper in this district with respect to Teva USA pursuant to 28 U.S.C. §§ 1391(b) and 1400(b). Teva USA denies the remaining allegations set forth in Paragraph 10 of the Complaint.

11. Teva USA admits that to introduce a drug that has not previously been approved by the FDA into interstate commerce, a new drug application ("NDA") must be submitted to the FDA, including information required under 21 U.S.C. § 355(b). Teva USA otherwise denies the allegations set forth in Paragraph 11 of the Complaint to the extent they are inconsistent with the law. Teva USA further denies the remaining allegations set forth in Paragraph 11 of the Complaint.

12. Teva USA admits that an abbreviated application process is available for approval to market a generic version of a listed drug, and that an abbreviated new drug application ("ANDA") must include information required under 21 U.S.C. § 355(j). Teva USA further admits that whether the FDA will consider a drug to be bioequivalent to a listed drug is at least partially governed by 21 U.S.C. § 355(j). Teva USA otherwise denies the allegations set forth in Paragraph 12 of the Complaint to the extent they are inconsistent with the law.

13. Teva USA admits that 21 U.S.C. § 355(j) does not require that an ANDA contain all of the same information required in an NDA. Teva USA further admits that 21 U.S.C.

§ 355(j) at least partially governs what information must be included in an ANDA. Teva USA otherwise denies the allegations set forth in Paragraph 13 of the Complaint to the extent they are inconsistent with the law. Teva USA further denies the remaining allegations set forth in Paragraph 13 of the Complaint.

14. Teva USA admits that according to 21 U.S.C. § 355(j), an ANDA must contain information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a listed drug. Teva USA otherwise denies the allegations set forth in Paragraph 14 of the Complaint to the extent they are inconsistent with the law.

15. Teva USA admits that according to 21 U.S.C. § 355(a), no person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to 21 U.S.C. § 355(b) or (j) is effective with respect to such drug. Teva USA otherwise denies the allegations set forth in Paragraph 15 of the Complaint to the extent they are inconsistent with the law.

16. Teva USA admits that Janssen Pharma is identified by the FDA as the holder of approved NDA No. 21-169 for galantamine hydrobromide tablets in dosages of Eq. 4 mg base, 8 mg base, and 12 mg base. Teva USA further admits that February 28, 2001 is the date identified by the FDA as the date on which NDA No. 21-169 was approved. Teva USA further admits that the sole indication of use for which galantamine hydrobromide tablets are approved by the FDA in NDA No. 21-169 is the treatment of mild to moderate dementia of the Alzheimer's type. Teva USA denies the remaining allegations set forth in Paragraph 16 of the Complaint.

17. Teva USA admits that a commercial formulation of galantamine hydrobromide approved by the FDA for the treatment of mild to moderate dementia of the Alzheimer's type is

sold under the trademarks RAZADYNE<sup>®</sup> and/or REMINYL<sup>®</sup>. Teva USA states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 17 of the Complaint, and on that basis denies the allegations set forth therein.

18. Teva USA admits that the '318 patent is listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluation" (the "Orange Book") in connection with the NDA No. 21-169.

19. Teva USA admits it has not previously challenged the listing of the '318 patent in the Orange Book. Teva USA denies that the '318 patent has any valid claims for an approved use of the drug product that is the subject of NDA No. 21-169 such that it qualifies for listing in the Orange Book. Teva USA further denies the remaining allegations set forth in Paragraph 19 of the Complaint.

20. Teva USA admits that it has represented that on or before April 22, 2005, it submitted to the FDA ANDA No. 77-587 and paragraph IV certifications under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) for galantamine hydrobromide tablets bioequivalent to the commercial formulation of galantamine hydrobromide marketed under the trademarks RAZADYNE<sup>®</sup> and/or REMINYL<sup>®</sup>. Teva USA further admits that it filed the ANDA and paragraph IV certifications to obtain approval under 21 U.S.C. § 505(j) to engage in the commercial manufacture and sale of its proposed galantamine hydrobromide tablets before the expiration of the patents listed in the Orange Book for NDA No. 21-169. Teva USA further admits that if it obtains such approval from the FDA for ANDA No. 77-587 it intends to market in the United States the galantamine hydrobromide products described in the ANDA, and that such marketing may occur before the

expiration of the '318 patent. Teva USA denies the remaining allegations set forth in Paragraph 20 of the Complaint.

21. Teva USA admits that the condition of use for which its seeks approval in its ANDA No. 77-587 for its proposed galantamine hydrobromide tablets is the treatment of mild to moderate dementia of the Alzheimer's type, the same condition of use as that approved in NDA No. 21-169. Teva denies the remaining allegations set forth in Paragraph 21 of the Complaint.

22. Teva USA admits that the indication set forth in the proposed labeling submitted by Teva USA in its ANDA No. 77-587 for its proposed galantamine hydrobromide tablets is the treatment of mild to moderate dementia of the Alzheimer's type, the same indication as that set forth in the approved labeling for the commercial formulation of galantamine hydrobromide which is marketed under the trademarks RAZADYNE<sup>®</sup> and/or REMINYL<sup>®</sup>. Teva USA denies the remaining allegations set forth in Paragraph 22 of the Complaint.

23. Teva USA realleges its responses to the allegations contained in Paragraphs 1-22 above as if fully set forth herein.

24. Teva USA admits that United States Patent No. 4,663,318 (the '318 patent) is entitled "Method of Treating Alzheimer's Disease" and states on its face that it was issued May 5, 1987. Teva USA states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 24 of the Complaint, and on that basis denies the remaining allegations.

25. Teva USA states that it is without knowledge or information sufficient to form a belief as to the truth of the allegation set forth in Paragraph 25 of the Complaint, and on that basis denies the allegation set forth therein.

26. Teva USA admits that a commercial formulation of galantamine hydrobromide is marketed under the trademarks RAZADYNE<sup>®</sup> and/or REMINYL<sup>®</sup>. Teva USA denies that the conditions of use for which the commercial formulation of galantamine hydrobromide is approved falls within one or more valid claim of the '318 patent. Teva USA states that it is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 26 of the Complaint, and on that basis denies the remaining allegations set forth therein.

27. Teva USA states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 27 of the Complaint, and on that basis denies the allegations set forth therein.

28. Teva USA denies the allegations set forth in Paragraph 28 of the Complaint.

29. Teva USA denies the allegations set forth in Paragraph 29 of the Complaint.

30. Teva USA denies the allegations set forth in Paragraph 30 of the Complaint.

31. Teva USA denies the allegations set forth in Paragraph 31 of the Complaint.

32. Teva USA admits that it had knowledge of the '318 patent prior to filing ANDA No. 77-587. Teva USA denies that this knowledge can or does form the basis for a finding of willful infringement and as such denies the remaining allegations set forth in Paragraph 32 of the Complaint.

33. Teva USA denies the allegations set forth in Paragraph 33 of the Complaint.

#### **First Defense**

34. The manufacture, use, offering for sale, sale or importation of the galantamine hydrobromide tablets that are the subject of ANDA No. 77-587 will not infringe directly or indirectly any valid claim of the '318 patent.

35. Teva USA's filing of its ANDA No. 77-587 did not infringe any valid claim of the '318 patent.

**Second Defense**

36. Each claim of the '318 patent is invalid for failure to satisfy one or more of sections 101, 102, 103, 112, and 116 of Title 35 of the United States Code.

**Third Defense**

37. At least one of the Plaintiffs lacks standing to assert infringement of the '318 patent by Teva USA.

**PRAYER FOR RELIEF**

WHEREFORE, defendant Teva Pharmaceuticals USA, Inc. respectfully requests that:

- a) The Complaint of Plaintiffs Janssen Pharmaceutica N.V., Janssen, L.P., and Synaptech, Inc. be dismissed with prejudice;
- b) The filing of Teva USA's ANDA No. 77-587 be found not to infringe any valid claims of the '318 patent;
- c) The manufacture, use, offering for sale, sale or importation into the United States of Teva USA's galantamine hydrobromide tablets that are the subject of Teva USA's ANDA No. 77-587 be found not to infringe any valid claims of the '318 patent;
- d) The '318 patent be found invalid;
- e) Teva USA be awarded its costs in this action;
- f) Teva USA be awarded its attorneys' fees pursuant to 35 U.S.C. § 285; and
- g) Teva USA be awarded such other and further relief as this Court may deem just and proper.

**COUNTERCLAIMS**

**Jurisdiction and Venue**

1. These counterclaims seek declaratory judgments pursuant to 28 U.S.C. §§ 2201 and 2202.

2. This Court has jurisdiction over these counterclaims pursuant to Title 35 U.S.C. and 28 U.S.C. §§ 1331 and 1338(a).

3. Venue is proper in this Court pursuant to 28 U.S.C. § 1391.

4. A justiciable controversy exists between the parties hereto with respect to validity, scope, and infringement of certain claims of U.S. Patent No. 4,663,318 (“the ‘318 patent”).

**Acts Giving Rise to this Action**

5. On information and belief Janssen Pharma is the holder of approved NDA No. 21-169 for galantamine hydrobromide tablets in dosages of Eq. 4 mg base, 8 mg base, and 12 mg base.

6. On information and belief Janssen Pharma caused the ‘318 patent to be listed in the FDA publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluation” (the “Orange Book”) as a patent which claims the drug for which Janssen Pharma submitted NDA No. 21-169 or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug, or in the method of using the drug. On information and belief, Synaptech, Inc. is the record owner of the ‘318 patent and Janssen Pharma is the exclusive licensee.

7. Teva USA submitted its ANDA No. 77-587 to obtain FDA approval to engage in the commercial manufacture, use and sale of Eq. 4 mg base, 8 mg base, and 12 mg base galantamine hydrobromide tablets, prior to the expiration of the ‘318 patent.

8. Teva USA sent letters dated April 22, 2005 (“Notification Letters”) to Janssen Pharmaceutica N.V., Janssen Pharmaceutica Products, L.P., and Synaptech, Inc., notifying each that Teva USA’s ANDA No. 77-587 was received by the FDA, and that Teva USA’s ANDA contained a “paragraph IV certification” that the ‘318 patent is invalid, unenforceable and/or will

not be infringed by the commercial manufacture, use, or sale of the product described in Teva USA's ANDA.

9. On June 3, 2005, Plaintiffs filed the instant suit asserting infringement of the '318 patent.

10. Plaintiffs' filing of the Complaint has created a reasonable apprehension on the part of Teva USA that Janssen Pharmaceutica N.V., Janssen, L.P., and/or Synaptech, Inc. will assert that Teva USA's making, using, selling, offering to sell, or importing of the product described in Teva USA's ANDA No. 77-587 infringes or will infringe the '318 patent.

#### **First Counterclaim**

11. Teva USA realleges the allegations contained in the preceding paragraphs as if fully set forth herein.

12. The manufacture, use, offer to sell, sale, and/or importation into the United States of the galantamine hydrobromide tablets that are the subject of Teva USA's ANDA No. 77-587 will not infringe directly or indirectly any valid claim of the '318 patent. Nor did the filing of Teva USA's ANDA infringe any valid claim of the '318 patent.

#### **Second Counterclaim**

13. Teva USA realleges the allegations contained in the preceding paragraphs as if fully set forth herein.

14. The '318 patent is invalid for failure to satisfy the provisions of one or more of sections 101, 102, 103, 112, and 116 of Title 35 of the United States Code.

#### **PRAYER FOR RELIEF**

WHEREFORE, defendant Teva Pharmaceuticals USA, Inc. respectfully requests that:

- a) The filing of Teva USA's ANDA No. 77-587 be declared not to infringe any valid claim of the '318 patent;

- b) The manufacture, use, offer to sell, sale, and/or importation into the United States of Teva USA's galantamine hydrobromide tablets that are the subject of Teva USA's ANDA No. 77-587 be declared not to infringe any valid claim of the '318 patent;
- c) The '318 patent be declared invalid;
- d) Teva USA be awarded its costs in this action;
- e) Teva USA be awarded its attorneys' fees pursuant to 35 U.S.C. § 285; and
- f) Teva USA be awarded such other and further relief as this Court may deem just and proper.

Respectfully submitted,



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Dated: June 23, 2005

**CERTIFICATE OF SERVICE**

I, Adam W. Poff, Esquire, hereby certify that on June 23, 2005, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:


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I further certify that on June 23, 2005, I caused a copy of the foregoing document to be served by hand delivery on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

**BY FEDERAL EXPRESS**

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